K123155

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitted by : Oct /31/2013

Sunbyung, Lee / Manager / Quality assurance team
SHINHUNG MST Co., Ltd
1642-8, Donghwa-Ri, Munmak-Eup, Wonju-Si, Gangwon-Do, 220-878, South Korea
Phone : +82-33-730-1900 Fax : +82-33-730-1919

2. Device Name :

Trade Name	:	Luna Dental Implant System
Common Names	:	Endosseous Dental Implant
Classification Name	:	Implant, Endosseous, Root-Form

3. Predicate Device :

3.1 Dentium Implantium (K041368)
Manufactured by **Dentium Co., Ltd**
3.2 Implantium Prosthetics(K052957)
Manufactured by **Dentium Co., Ltd**

OCT 3 1 2013

4. Device Description :

The Luna Dental Implant System is a device of pure titanium(ASTM F67) and titanium alloy(ASTM F136) intended to be surgically placed in the bone of the upper or lower arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It consists of fixture, abutment, mount, mount screw, cover screw. The fixture's surface is S.L.A(Sand-Blasted, Large Grit, Acid-etched) Its materials, dimension, and intended use are similar to devices currently marketed worldwide. The Luna Dental Implant System fixture and healing abutment are supplied with gamma sterilization.

Fixtures consisted of mount type and mount free type. Abutments consisted of simple abutment, hex and non-hex duo abutment, hex and non-hex angled abutment (15° & 25°), hex and non-hex contour abutment, hex and non-hex temporary abutment, screw abutment with titanium cylinder, ball abutment with socket

assembly, healing abutment, screw abutment screw, and abutment screw. Fixture dimension is 3.7mm x 8.5-15mm and 4.2mm – 5.7mm x 7.0mm – 15mm and Abutment diameter is 4.0mm ~ 6.0mm

5. Intended For Use :

The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function

6. Substantial Equivalence :

Device Name	**Subject Device**	**Predicate Device**	
Manufacturer	SHINHUNG MST Co., Ltd	Dentium Co., Ltd	Dentium Co., Ltd
510(k) Number	New	K041368	K052957
Materials	Titanium, Titanium Alloy	Titanium, Titanium Alloy	Titanium, Titanium alloy, Gold alloy
Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Abutment, Dental, Endosseous, implants
Indications for use	The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function	The Dentium Co., Ltd Implantium is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function	Intended for use as an aid in prosthetic rehabilitation.
Use	Prescription	Prescription	Prescription
Sterilization	It is supplied sterile(Gamma radiation)	It is supplied sterile(Gamma radiation)	It is supplied Non-sterile

The comparison between Luna Dental Implant System and other predicated devices is claimed to be substantially equivalence in terms of indication for use, materials, product form, technology, and performance specifications.

The difference between Luna Dental Implant System and predicate devices are the product shape and slight mechanical and physical characteristics. However, the slight differences do not affect to the application of the device. Therefore, we state that Luna Dental Implant System is substantially equivalent to the predicate devices

7. Performance Testing

Biocompatibility testing on the proposed Luna Dental Implant System has been completed. Requirements for biological evaluation of the proposed device were based on the ISO7405(2008), "Dentistry-Evaluation of biocompatibility of medical devices used in dentistry." The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following biocompatibility tests were completed

-ISO Cytotoxicity	-ISO Systemic toxicity
-ISO Pyrogenicity	-ISO Sensitization
-ISO Intracutaneous reactivity	-ISO Implantation

The proposed -ISO Sensitization was evaluated using the following performance bench testing to confirm the performance characteristics:

-ISO Static compressive	-ISO Fatigue
-Torque Force	-Adaptation Accuracy
-Rotational shear strength	-Loosening torque

8. Review

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Luna Dental Implant System met the established specifications necessary for consistent performance according to its intended use.

Luna Dental Implant System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification SHINHUNG MST Co., Ltd concludes that the Luna Dental Implant System is substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2013

SHINHUNG MST Company, Limited
Sunbyung Lee
Team Leader
1642-8, Donghwa-Ri, Munmak-Eup
Wonju-Si, Gangwon-Do 220-878
REPUBLIC OF KOREA

Re: K123155
Trade/Device Name: Luna Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: August 26, 2013
Received: August 30, 2013

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for use Statement

510(k) Number (If known) : K123155

Device Name : Luna Dental Implant System

Indication for use :

The Luna Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient' s chewing function

Prescription Use X AND/OR **Over-The-Counter** _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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